United States
Environmental Protection
Agency

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MEMORANDUM

SUBJECT: **Ecological Risk Assessment for two products, Nalco 60615 and Nalco 60630, which are end-use products containing urea. The proposed registration of these products is for use in controlling microorganisms in an in-situ generating system for use in pulp and paper mills.**

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I. INTRODUCTION

The Risk Assessment and Science Support Branch (RASSB) has reviewed Nalco Company's request to obtain a section 3 registration for two antimicrobial products that will be used in an in-situ generating system to control microorganisms in pulp and paper mill water systems. The two products are Nalco 60615, which contains urea at a concentration of 15.0% and Nalco 60630, which contains urea at a concentration of 30.0%. The urea is considered to be the active ingredient of the products. These urea products are proposed to be mixed with sodium hypochlorite. The registrant has submitted waiver requests for the ecological data requirements for the two urea-based products, Nalco 60615 and Nalco 60630.

Based on the use pattern of these products, Nalco 60615 and Nalco 60630 are not expected to result in acute or chronic risk to terrestrial birds, mammals, or plants or to aquatic species under typical use conditions due to a lack of exposure based on being used indoors in pulp and paper mill water systems. Although traces of oxidative residues in the waste water may be discharged into the holding ponds or lagoons of the paper mill, these will rapidly degrade/react and will not enter aquatic or terrestrial environments. As endangered species are not expected to be exposed, a quantitative or more refined endangered species effect determination is not necessary at this time. No additional ecological testing will be required.

ECOTOXICITY

Acute Ecotoxicity Studies for Nalco 60615 and Nalco 60630 (urea):

No studies were submitted by the registrant. The registrant submitted waiver requests for the required studies and an EcoSAR analysis. The basis of the waiver request is that urea and sodium hypochlorite are combined in a reaction vessel of the OxiPRO closed system at the pulp and paper mill and the reaction of these two chemicals produces chlorourea. In order to increase yields of chlorourea and to maintain its stability in the OxiPRO reaction vessel, the reaction vessel has to be highly alkaline (pH $\geq$12.0). The chlorourea is fed into and mixed with the paper/paperboard water system which typically has a pH of 7-8.5. Chlorourea is a relatively unstable compound that degrades to hypochlorous acid. As per the chemistry memorandum by A.N. Shamim (5/18/11, D385694 and D386118), if small amounts of chlorourea or hypochlorous acid are discharged in the pulp and paper mill system water, they will quickly react/degrade in the lagoons or holding ponds and, therefore, will not enter aquatic or terrestrial environments.

The results of an EcoSAR 1.00a (2009) identified the structure of chlorourea as being a member of the amide class of chemicals. The resulting estimated acute LC_{50}/EC_{50}'s for fish, daphnid and green algae were 9150, 1468 and 2 mg/L, respectively. The ChV's for fish, daphnid and green algae were 54, 19 and 0.16 mg/L, respectively.

The results of the EcoSAR 1.00, a 2002 version of the SAR test that contains the Haloamine class, identified the structure of chlorourea as being a member of the Haloamine (oxidizing agent) class. The resulting estimated acute LC_{50}/EC_{50}'s for fish, daphnid and green algae were all <1.0 mg/L and the ChV's for fish, daphnid and green algae were all <0.10 mg/L. These results indicate that chlorourea would be highly toxic to aquatic organisms if it were to contaminate an aquatic environment which, again, is not expected.

The acute toxicities estimated using the two EcoSAR versions were disparate. The Agency cannot determine which estimates are likely to better reflect the true ecotoxicity of chlorourea because there are no chemical-specific acute toxicity studies for comparison, because there is typically a great deal of error in the estimates, and there is uncertainty regarding which EcoSAR class of chemicals (amide or haloamine), if either, is the most appropriate to include chlorourea. Therefore, neither set of modeled acute ecotoxicity estimates is considered to be appropriate at this time. However, as exposure of endangered species is not expected, a

quantitative or refined risk determination is not necessary at this time.

II. ESTMATED ENVIRONMENTAL CONCENTRATIONS (EECs)

A. EECs – TERRESTRIAL

Terrestrial EECs were not calculated since it is anticipated that exposures and risks to terrestrial animals (birds and mammals) from use of the Nalco products would be minimal and any incidental exposure would be practically non-toxic on an acute basis. Terrestrial plants are also not expected to be at risk.

B. EECs – AQUATIC

Aquatic EECs were not calculated since it is anticipated that exposures and risks to aquatic organisms from use of the Nalco products would be minimal and any incidental exposure would be practically non-toxic on an acute basis. As per the chemistry memorandum by A.N. Shamim (5/18/11, D385694 and D386118), if small amounts of chlorourea or hypochlorous acid are discharged in the pulp and paper system water, they will quickly degrade/react in the lagoon and, therefore, will not enter aquatic environments.

III. RISK QUOTIENTS (RQs) AND LEVELS OF CONCERN (LOCs)

A. OVERVIEW

Exposure and Risk to Nontarget Terrestrial Animals and Aquatic Organisms

Risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. The means of this integration is called the quotient method. Risk quotients (RQs) are calculated by dividing exposure estimates by acute and chronic ecotoxicity values.

RQ = EXPOSURE/TOXICITY

RQs are then compared to OPP's levels of concern (LOCs). These LOCs are used by OPP to analyze potential risk to nontarget organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. LOCs currently address the following risk presumption categories: (1) **acute** -- potential for acute risk to non-target organisms which may warrant regulatory action in addition to restricted use classification; (2) **acute restricted use** -- the potential for acute risk to non-target organisms, but may be mitigated through restricted use classification; (3) **acute endangered species** - endangered species may be adversely affected by use; (4) **chronic risk** - the potential for chronic risk may warrant regulatory action, endangered species may potentially

be affected through chronic exposure; (5) **non-endangered plant risk** – potential for effects in non-endangered plants; and (6) **endangered plant risk** – potential for effects in endangered plants. Currently, AD does not perform assessments for chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk from granular/bait formulations to birds or mammals.

The ecotoxicity test values (measurement endpoints) used in the acute and chronic risk quotients are derived from required studies. Examples of ecotoxicity values derived from short-term laboratory studies that assess acute effects are: (1) LC_{50} (fish and birds); (2) LD_{50} (birds and mammals); (3) EC_{50} (aquatic plants and aquatic invertebrates); and (4) EC_{25} (terrestrial plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies that assess chronic effects are: (1) LOAEC (birds, fish, and aquatic invertebrates) and (2) NOAEC (birds, fish and aquatic invertebrates). For birds and mammals, the NOAEC generally is used as the ecotoxicity test value in assessing chronic effects, although other values may be used when justified. However, the NOAEC is used if the measurement endpoint is production of offspring or survival.

Risk presumptions and the corresponding LOCs are tabulated below (Table 3).

Table 3. Risk Presumption Categories

Risk Presumption for Terrestrial Animals	**LOC**
Acute: Potential for acute risk for all non-target organisms	>0.5
Acute Restricted Use: Potential for acute risk for all non-target organisms, but may be mitigated through restricted use classification	>0.2
Acute Endangered Species: Endangered species may be adversely affected by use	>0.1
Chronic Risk: Potential for chronic risk may warrant regulatory action	>1
Risk Presumption for Aquatic Organisms	**LOC**
Acute: Potential for acute risk for all non-target organisms	>0.5
Acute Restricted Use: Potential for acute risk for all non-target organisms, but may be mitigated through restricted use classification	>0.1
Acute Endangered Species: Endangered species may be adversely affected by use	>0.05
Chronic Risk: Potential for chronic risk may warrant regulatory action	>1
Risk Presumption for Terrestrial and Aquatic Plants	**LOC**
Potential for risk for all non-endangered and endangered plants	>1

B. RQs – TERRESTRIAL

Terrestrial RQs were not calculated since RASSB believes that exposures and risks for terrestrial animals (birds and mammals) and plants to the Nalco urea products during and after use in pulp and paper mills would be minimal. No toxic degradates are expected to contaminate terrestrial environments due to the unstable, reactive nature of chloramine and hypochlorous acid.

C. RQs – AQUATIC

Aquatic RQs were not calculated since RASSB believes that exposures and risks for aquatic organisms following use of the Nalco urea products in pulp and paper mills would be negligible because, if small amounts of chlorourea or hypochlorous acid are discharged in the system water, they will quickly degrade/react in the lagoons and, therefore, will not enter aquatic or terrestrial environments.

IV. LISTED SPECIES AND CRITICAL HABITAT REVIEW

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species." **50 CFR §402.02**.

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If it is determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

This preliminary assessment indicates that there is the potential for the proposed Nalco 60615 and Nalco 60630 use areas to co-occur with listed species. However, there is no need to conduct a more refined endangered species effect determination because exposure of listed species is not expected to occur due to the low use concentration of chlorourea, the rapid degradation of any discharged chlorourea or hypochlorous acid, and the low toxicity of the resulting degradates.

V. SUMMARY

In summary, RASSB concludes that, based on the available information and data, which was minimal, the Nalco urea products are not expected to come into contact with nontarget species. The Nalco chemicals are used in a closed reaction chamber in pulp and paper mills (indoors) and the chlorourea resulting is metered into the mill water system. Any chlorourea or hypochlorous acid remaining in the waste water would be present at low levels and, being short-lived and reactive, are not expected to survive beyond the holding ponds/lagoons to result in exposure of nontarget organisms. Therefore, no additional testing is required for these chemicals.

Urea is the labeled active ingredient in Nalco 60615 and Nalco 60630 which is mixed with sodium hypochlorite in a closed system at pH $\geq$12. The reaction of the two yields chlorourea which is metered into the pulp and paper water system. In the water system, chlorourea degrades to hypochlorous acid. As noted above, environmental exposure to chlorourea and hypochlorous acid is not expected and, hence, there is no ecological risk resulting from registration of urea when used in paper/paperboard water systems following reaction with sodium hypochlorite at about a 1:1 N:Cl molar ratio in a closed system at pH $\geq$12.

VI. ADDITIONAL DATA NEEDED TO REFINE THE ASSESSMENT

No additional data are needed.

VII. LABEL ISSUES:

No additional label statements are necessary.

VIII. BIBLIOGRAPHY

A. Najm Shamim. 5/18/11. Nalco Company's Proposed Registration of Nalco 60615 and Nalco 60630 Slimicides Containing Urea for Use in Paper and Paperboard Water Systems: Chemistry, Chemical Processes and Characterization of Transformation Products. D385694 and D386118.